REMARKS

Claims 28, 35-37, 40-41 and 43 are pending and under examination in the present application. Non-limiting amendments have been made to claim 40 solely to advance the prosecution of the application. In view of the following remarks, applicants respectfully request reconsideration and withdrawal of the rejections and objections set forth in the Office Action.

Priority

Applicants thank the Examiner for noting the required reference for priority in the present application. Applicants have amended the application to include the required priority claim.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

In the Office Action, claims 40 and 43 were "rejected under 35 U.S.C. 112, second paragraph, as being indefinite[.]" Specifically, claim 40 was rejected for including the language "the form of..." Claim 40 has been amended in non-limiting fashion to remove the phrase "the form of..."

Claim 43 was rejected for because it "appears to be drawn more to a process claim rather than a composition claim" by including the phrases "the content of the corresponding lactam" and "the initial amount". Applicants respectfully submit that claim 43 is a composition claim that contains functional elements relating to the stability of the solid composition which is explicitly permitted by MPEP §21735.05(g). Additionally, one skilled in the art readily understands the scope of the claim and can ascertain whether a composition is covered by claim 43. Accordingly, applicants respectfully request the Examiner withdraw this rejection because claim 43

> apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent.

MPEP §2173.02

In light of the above, applicants respectfully request the Examiner withdraw these rejections.

Claim Rejections - 35 U.S.C. §102

In the Office Action claims 28, 36, 40-41 and 43 were "rejected under 35 U.S.C. 102(e) as being anticipated by Lan (20020037926)" because

> Lan discloses at paragraph:
>
> [0028] Gabapentin and pregabalin can be formulated to provide greater stability to the compound. Useful excipients for inclusion with gabapentin and pregabalin include neutral amino acids, such as glycine and L-valine; and humectants, such as ethylene glycol, propylene glycol and glycerine. The active compounds may also be coated as agglomerated powders with a polymer such as polyvinyl pyrrolidone to provide better stability and processing characteristics.

Applicants respectfully disagree with this rejection because the priority date for the present claims predates the prior art date of paragraph [0028] cited above in Lan (20020037926). The present claims are supported by at least the May 10, 1999, PCT filing on which the U.S. filing is based. In contrast paragraph [0028] of Lan cited in the Office Action appears to only be entitled to Lan's April 10, 2000, PCT filing date, which is after the priority date of the claimed invention. Provisional application 60/128,543 on which Lan (20020037926) is based does not include the paragraph cited in the Office Action and does not appear to use the term "humectant" or disclose propylene glycol.

Accordingly, applicants respectfully submit that Lan (20020037926) is not prior art to the present claims and respectfully request the Examiner withdraw this rejection.

Claims 28, 36, 40 and 41 were "rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative under 35 U.S.C. 103(a) as obvious over Schrier et al. (WO 98/58,641)."

Applicants believe the Office Action is overstating the disclosure of WO 98/58,641 as anticipating or rendering obvious the present claims. The present claims are directed to a solid composition comprising pregabalin or gabapentin and a specific humectant, propylene glycol. The compositions disclosed in WO 98/58,641 may be solid or liquid and the carriers may be any number of things. Additionally, WO 98/58,641 does not specifically set out the claimed solid dosage form of pregabalin or gabapentin and propylene glycol. Applicants also note that in the list of carriers cited from WO 98/58,641 propylene glycol is listed between vegetable oils and water, which suggests to

those skilled in the art that propylene glycol is provided as a carrier for a liquid dosage form. Accordingly, WO 98/58,641 does not specifically disclose the claimed compositions and does not suggest that the inclusion of propylene glycol into solid compositions of gabapentin or pregabalin would provide any stabilizing effect.

In the Office Action claims 28, 36, 40 and 41 were "rejected under 35 U.S.C. 102 (f or g) as anticipated by or, in the alternative under 35 U.S.C. 103(a) as obvious over Schrier et al (USP 6,329,429)." Applicants note that U.S. patent no. 6,329,429 is a national stage application of WO 98/58,641 discussed above and that the disclosures of these references appear to be identical. Accordingly, applicants respectfully submit that the rejected claims are not anticipated or rendered obvious by U.S. patent no. 6,329,429 for the reasons discussed above. Additionally, applicants respectfully submit that the subject matter claimed in the present application and U.S. patent no. 6,329,429 is not conflicting further for the reasons discussed below.

Claims 28, 36, 40 and 41 were also "rejected on the ground of nonstatutory double patenting over claims 1 and 8 of U.S. patent no. 6, 329,429[.]" Applicants traverse this rejection because claims 1 and 8 of U.S. patent no. 6, 329,429 do not anticipate or render obvious the claims in the present application.

According to the MPEP:

> Since the doctrine of double patenting seeks to avoid unjustly extending patent rights at the expense of the public, the focus of any double patenting analysis necessarily is on the **claims** in the multiple patents or patent applications involved in the analysis…

MPEP §804 (emphasis added).

Additionally

> A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting **claims** are not identical, but at least one examined application **claim** is not patentably distinct from the reference **claim(s)** because the examined application claim is either anticipated by, or would have been obvious over, the reference **claim(s)**.

MPEP §804 II.B.1. (emphasis added).

The claims in the present application are directed to a stabilized solid composition comprising pregabalin or gabapentin and propylene glycol. In contrast, claims 1 and 8 of U.S. patent no. 6, 329,429 are for "method[s] for preventing and treating inflammatory disease[.]" Additionally, neither of claims 1 and 8 of U.S. patent no. 6, 329,429 make any reference to propylene glycol or stabilized solid compositions. Accordingly, claims 1 and 8 of U.S. patent no. 6, 329,429 cannot anticipate the present claims or render them obvious and applicants respectfully request the Examiner withdraw this rejection.

Claims 28, 35 to 37, 40 to 41 and 43 were also "rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wallace (US 5,025,035) or 5,084,479 (Woodruff). Applicants respectfully traverse these rejections for the same reason as WO 98/58,641 discussed above. In fact, the sections of the patents cited in the Office Action appear to be virtually identical to that in WO 98/58,641. Example 3 of U.S. patent no. 5,025,035 cited in the Office Action also makes no mention of propylene glycol.

In light of the above, applicants respectfully request the Examiner withdraw these rejections.

Claim Rejections - 35 U.S.C. §103

In the Office Action claims 28, 35-37, 40-41 and 43 were "rejected under 35 U.S.C. 103(a) as being obvious over Augart et al (US 6,054,482) in view of any one of Giacin (US5302373), Herget (US5618342) or Baschang (4666886)."

Applicants respectfully submit that this rejection is based on an impermissible hindsight analysis of the cited references. Again, the present claims are directed to a stabilized solid composition comprising pregabalin or gabapentin and propylene glycol. U.S. patent no. 6,054,482 does not mention propylene glycol but discussed stability and concluded

> that the cause of the lactam formation was apparently also the catalytic effects of adjuvant materials which also did not follow any recognizable logic. In order to establish which adjuvant materials promote the lactam formation, **laborious** serial investigations had, therefore, to be carried out.

Column 4, lines 58 to 64

U.S. patent no. 6,054,482 then went on to discuss two experiments with PEG that produced opposite results when it stated

> in the case of the use of polyethylene glycol (PEG), cyclization to the lactam took place to a considerable extent. In another test series with very pure active substance, PEG was found to be indeed usable as an excipient.

Column 5, lines 1 to 4.

Accordingly, U.S. patent no. 6,054,482 demonstrated that that the stabilizing effects of PEG were at best ambiguous and that the destabilizing "catalytic effects of adjuvant materials… did not follow any recognizable logic" so that "laborious serial investigations had, therefore, to be carried out." U.S. patent no. 6,054,482 therefore states to those skilled in the art that there is no predictability in using adjuvants to stabilize formulations, and that there is no logic that can be used to extrapolate results to other materials. Moreover, column 5, lines 11-17 and claims 4 and 8 of U.S. patent no. 6,054,482 provide a list of suitable excipients. However, this list does not include PEG. Accordingly, U.S. patent no. 6,054,482 provides no motivation for one skilled in the art to focus on PEG and no predictability of success or failure even when using PEG.

Regarding U.S. patent no. 5,302,373, that patent stated that "[s]uitable humectant compounds include propylene glycol" but makes no mention of PEG. Column 2, lines 29 to 33. Accordingly it cannot teach that propylene glycol is a functional equivalent of PEG.

Moving to U.S. patent no. 5,618,342, that patent disclosed PEG and polypropylene glycol as humectants. Column 2, lines 37 to 41. However, one skilled in the art recognizes that polypropylene glycol is not the same as propylene glycol, and therefore that U.S. patent no. 5,618,342 does not teach that PEG and polypropylene glycol are functional equivalents.

Finally, U.S. patent no. 4,666,886, discloses that PEG and propylene glycol are humectants, but only in the context of ointments and creams. Nothing motivates the reader to combine the teachings of U.S. patent no. 4,666,886 with those of U.S. patent no. 6,054,482 which, as already noted, teaches that the art is unpredictable.

Accordingly, applicants respectfully submit that the claims are not rendered obvious over the cited references, and request the Examiner withdraw this rejection.

CONCLUSION

In view of the above remarks and amendments, applicants respectfully submit that this application is in condition for allowance and earnestly solicit notice to that effect. The Examiner is invited to contact the undersigned at the telephone number provided below if the Examiner believes such would be helpful in advancing the application to issue.

Respectfully submitted,

Dated: 2/21/08

Robert N. Young
Reg. No. 48,412
P.O. Box 1027
St. Louis, MO 63006
Tel: (314) 274-4432
Fax: (314) 274-7256